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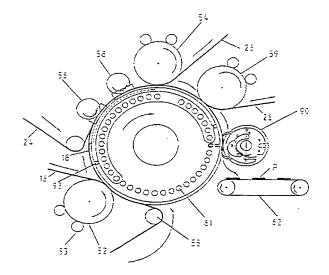
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(54) Apparatus for manufacturing medicinal pathes for percutaneous administration

(57)There is disclosed an apparatus for manufacturing medicinal patch for percutaneous administration and more particularly disclosed a main processing unit which performs processing steps such as half die cutting, mutual bonding and die cutting on the base film strip and adhesive tape strip both of which are main stuffs to be used in making the medicinal patch according to the invention. a half-die cutting roller(52) to simultaneously half die cut the medicament layer and first elastic film layer laminated on a separate liner of a base film; a scrap winding roller(66) to collect the scrap of the medicament and first elastic film layers produced by half-die cutting; a pressing means(56, 58) to press the adhesive tape laminated the base film; another half-die cutting roller(54) performing half-die cutting on regions of the adhesive tape attached to the base film into an oval or round shape; a roller(74) on which a scrap of the adhesive tape produced by the half-die cutting is wound for removal; a die cutting roller(59) with a plurality of quadri-shaped die cutting blades equidistantly installed on its outer surface, performing a continuous die cutting of a resultant strip; a roller on which a scrap of the resultant strip, created by the die cutting is wound for removal; a main die roller(60) having a plurality of vacuum holes on its outer surface, and large diameter part of all the half die cut rollers and die cut roller being in rollable contact with the surface thereof; and a vacuum pad roller(90) for drawing up the finished products from the main die roller and transferring them to a conveyor are provided in order to perform the manufacturing steps according to present invention.



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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus for manufacturing medicinal patch for percutaneous administration and more particularly it relates to a main processing unit which performs processing steps such as half die cutting, mutual bonding and die cutting on the base film strip and adhesive tape strip both of which are main stuffs to be used in making the patch. Medicinal patches for percutaneous administration need capability to fulfill their physical requirements, that is, they have such capability as to adhere to the skin of the knee or elbow securely and elastically for a long period of time even during bath or shower bath, and be not easily contaminated by the dirt without loss of medicinal properties.

The patch provided by using the inventive apparatus can be accomplished by attaching a base film which contains medicinal properties over an adhesive tape through a series of manufacturing steps of the present invention. The base film which is used in making the patch of the invention has a structure of lamination of a separate liner, a medicament layer, a first elastic film layer and a first release liner in order, and the adhesive tape which is also used in making the patch of the invention has a structure of lamination of a second elastic film, an adhesive layer and a second release liner in order.

2. Discussion of Related Art

It has been reported that piroxicam, a non-steroidal anti-inflammatory and analgesic agent, shows competent efficacy against acute pain due to rheumatoid arthritis, osteoarthritis, and gout etc. when applied by oral administration but causes unfavorable side effects such as gastroenteric disorder, gastric or duodenal ulcer, and the like. In this sense, it is considerably advisable to apply piroxicam by other than oral administration, that is, such as by percutaneous administration.

In the medicinal patch for percutaneous administration, the preparations of its medicinal substrate are of course a matter of primary importance, and the physical characteristics of the patch are by no means the least importance if we are to achieve the desired efficacy of drug over the percutaneous administration. That is, aparting from what the composition of the medicinal substrate contained in the patch, the patch must securely adhere to an articulation such as the knee or elbow maintaining its elasticity even during bath or shower bath, and should be free from contamination and loss of medicinal properties. Further, the medicinal patch preferably has a round or oval shape and is thin and small so as to facilitate topical application thereof.

However, conventional medicinal patches in which medicaments are simply applied over a non-woven fabric or textile fail to meet the above requirements.

5 SUMMARY OF THE INVENTION

Accordingly, the present invention is directed to provide an apparatus for manufacturing medicinal patch for percutaneous administration that is thin and small in an oval or round shape to be securely and elastically adhered to the skin of the human body for a long period of time

To achieve these and other advantages and in accordance with the purpose of the present invention, as embodied and broadly described, there is disclosed an apparatus for manufacturing a medicinal patch for percutaneous administration comprising the following elements:

a half-die cutting roller(a second half-die cutting roller) to ovally or roundly half die cut the medicament layer and first elastic film layer simultaneously laminated on a separate liner of a base film, said half-die cutting roller having large-diameter cylindrical parts, a small-diameter cylindrical part formed between said large-diameter cylindrical parts and a plurality of ovally or roundly shaped kiss cutting blades equidistantly installed on the outer surface of said small-diameter cylindrical part.

a scrap winding roller around which a scrap of the medicament and first elastic film layers produced by half-die cutting is wound for removal;

a pressing means to press the adhesive tape laminated the base film on which ovally or roundly shaped medicament and first elastic film layers are formed by the second half-die cut so as to attach these with each other;

another half-die cutting roller(a third half-die cutting roller) which has a plurality of ovally or roundly half-die cutting blades equidistantly installed on its outer surface of small-diameter cylindrical part, performing continuous half-die cutting on regions of the adhesive tape attached to the base film into an oval or round shape, corresponding to the second half-die cut regions of the medicament and first elastic film layers;

a roller on which a scrap of the adhesive tape produced by the third half-die cutting is wound for removal;

a die cutting roller which has a plurality of quadrishaped die cutting blades equidistantly installed on its outer surface, performing a continuous die cutting of a resultant strip which has the separate liner, the oval or circular shaped medicament and first elastic film layers and the oval or circular shaped adhesive and second elastic film layers, into a quadri-shaped shape;

a roller on which a scrap of the resultant strip cre-

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ated by the die cutting is wound for removal;

a main die roller having a plurality of vacuum holes on its outer surface for drawing up the separate liner of the base film, and with the outer surface thereof large diameter parts of all the half die cut rollers and die cut roller being in rollably contact; and,

a vacuum pad roller having a plurality of rubber sucking means on its outer surface for drawing up the finished products from the main die roller and transferring them to a conveyor.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE ATTACHED DRAW-INGS

Figs. 1(a) and 1(b) are each a plan view of a medicinal patch provided in accordance with the present invention, and an enlarged-sectional view thereof as taken along the line a - a of Fig. 1(a).

Fig. 2(a) shows a perspective view of a base film roll used for making the inventive medicinal patch for percutaneous administration, and a sectional view thereof as taken along the line b - b.

Fig. 2(b) shows a perspective view of an adhesive tape roll used for the inventive medicinal patch for percutaneous administration, and a sectional view thereof as taken along the line c - c.

Fig. 3 schematically depicts steps of manufacturing the medicinal patch for percutaneous administration in accordance with the present invention.

Figs. 4(a) to 4(m) are each plan and sectional views of respective base film strip and/or adhesive tape strip or its scrap to be removed according to the steps of manufacture the medicinal patch in accordance with the present invention.

Fig. 5 is a front view of an apparatus for manufacturing medicinal patch for percutaneous administration in accordance with the present invention.

Fig. 6 shows an enlarged main part of the apparatus for manufacturing medicinal patch for percutaneous administration in accordance with the present invention.

Fig. 7 is a perspective view of the part B shown in Fig. 6.

Fig. 8 shows sectional views of main die roller and vacuum pad roller.

DETAILED DESCRIPTION OF PREFERRED EMBOD-IMENT

Reference will now be made in detail to the preferred embodiments of the present invention, examples of `which are illustrated in the accompanying drawings. Like reference numerals denote like reference parts throughout the specification and the drawings.

A preferable medicinal patch which obviates the drawbacks of the conventional art and fulfills the physical requirement of a transdermal skin patch is depicted in Figs. 1(a) and 1(b).

Fig. 1(a) is a plan view of the medicinal patch provided according to the present invention, and Fig. 1(b) is an enlarged-sectional view thereof as taken along the line a - a of Fig. 1(a). Reference numeral 1 designates a separate liner that is to be finally removed when the patch P is applied to the skin of the human body. The separate liner 1, being used as a releaser at the time of use, is favorably formed by coating silicon on such the resin as polyethylene terephthalate (PET) or paper. As can be seen from Fig. 1(b) which shows a section of the patch, on the separate liner 1 are deposited a medicament layer 3, a first elastic film layer 4, an adhesive layer 6 and a second elastic film layer 7 in order. The first elastic film layer 4 has an elasticity of more than about 100% and thickness of 5 to 300 micrometers and is preferably made from polyurethane (PU), polyethylene terephthalate (PET) or styrene iso-styrene (SIS), and

A base film 10 which is used as one of main stuffs in making the patch P of the invention is shown in Fig. 2(a) and has a structure of lamination of a separate liner 1, a medicament layer 3, a first elastic film layer 4 and a first release liner 5 in order. A adhesive tape 20 which is also used as another main stuff in making the patch of the invention has a structure of lamination of a second release liner 5', an adhesive layer 6 and a second elastic film 7 in order as can be seen in Fig. 2(b). The base film 10 and the adhesive tape 20 undergo a series of processing steps such as a few times half-die cutting, mutual bonding, die cutting and drawing-up etc. with the help of the apparatus of the present invention.

A method of manufacturing the base film 10 has been fully described in another korean patent application filed by us on the same date of priority of the present invention, entitled "Method of manufacturing a base film for a transdermal skin patch and an apparatus for making the same". Since the method of manufacturing the base film 10 itself is another invention and not material to understand the present invention, the detailed description thereabout is omitted in this specification. Furthermore, the description about a method of manufacturing the adhesive tape 20 itself is also omitted for the same reason.

Fig. 3 schematically depicts the steps of manufacturing the medicinal patch for percutaneous administration in accordance with the present invention and Figs. 4(a) to 4(m) are each plan and sectional views of respective base film strip and adhesive tape strip or its/their residual scrap/scraps to be removed in the process of the present invention.

Referring to Figs. 3 to 4(m), the steps of manufacturing the inventive medicinal patch are now fully described. Axis X of Fig. 3 indicates the development of





the manufacturing steps in accordance with the present invention.

FIRST STEP

The base film 10 which is provided with a form of roll and whose structure is a lamination of the separate liner 1, the medicament layer 3, the first elastic film layer 4 and the first release liner 5 in order is drawn out from one of first feed rollers 12 and 12' while the first release liner 5 is peeled off from the base film 10 for removal and wound around its winding roller 60 (Hereinafter the base film with no release liner 5 being preferably called 'released base film'). This step can be referred to Figs. 3, 4(a) and 4(b).

SECOND STEP

The released base film 10, being unwound from one of first feed rollers 12 and 12', passes through a pair of first half-die cutting rollers 14 and 14' so that at least one wave-shaped cut-and-tear line 2 is consecutively formed only on the separate liner 1 along the length of the released base film 10 as depicted in Figs. 3 and 4(c).

In the medicinal patch for percutaneous administration manufactured by using the inventive apparatus, each of the medicament layer 3 and the elastic film layers 4 and 7 is no more than a few tens of micrometers in thickness and the overall medicinal patch P is so thin that it is not easy to remove the separate liner 1 from the patch unless appropriate cut-and-tear line is provided therein when applying the patch to the diseased region of the body. Therefore, the second step is carried out for consecutively forming at least one cut-and-tear line 2 just on the separate liner 1 by the half-die cutting technique.

THIRD STEP

The medicament layer 3 and the first elastic film layer 4, overlapped on the separate liner 1 of the base film 10, are simultaneously half-die cut into an oval or round shape on a main die roller 60 through second half-die cutting. A scrap 16 of the medicament layer 3 and the first elastic film layer 4 created from the second half-die cutting is wound on a roller 66 to be removed from the separate liner 1, as shown in Figs. 3 and 4(d) and 4(e).

A first resultant strip 18 where the medicament layer 3 and the first elastic film layer 4 are remained in the shape of oval or circle on the separate liner 1 by said second half-die cutting and its consequent removal of the scrap 16, is transferred forward while maintaining close contact to the outer surface of the main vacuum die roller 60.

FOURTH STEP

The adhesive tape 20 which is prepared as a roll and whose structure is a lamination of the second release liner 5', the adhesive layer 6 and second elastic film layer 7 is continuously provided from a second feed roller 22 while its second release liner 5' being removed therefrom and collected on its winding roller 70 and, thus, makes a released adhesive tape 24 with no release liner 5'. After being peeled off the second release liner 5', the released adhesive tape 24 is then attached over the first resultant strip 18 where the medicament layer 3 and the first elastic film layer 4 are remained in the shape of oval or circle on the separate liner 1, which is well depicted in Figs. 3 and 4(f), 4(g), 4(h) and 4(i).

The fourth step is also carried out on the main die roller 60 with the help of pressing rollers 56 and 58 which give attaching pressure to the first resultant strip 18 against the main die roller 60 right after the released adhesive tape strip 24 is laid over the first resultant strip 18.

FIFTH STEP

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From this step, the released adhesive tape 24 which has been attached over the first resultant strip 18 are manipulated to have the coincidental oval or circular shape just on the corresponding oval or circular medicament layer 3 and the first elastic film layer 4 by a third half-die cutting. However, it should be noted that the oval or circular regions of the adhesive tape 24 have the same shapes as those of the medicament layer 3 and the first elastic film layer 4 of the first resultant strip 18 but are a little larger than the medicament layer 3 and the first elastic film layer 4 so as to let the differentiated larger area have a role of adhering capability to the skin. A scrap 26 of the released adhesive tape produced at this point is removed by being wound on a roller 74, thus, creating a second resultant strip 30. This process can be well referred to in Figs. 3, 4(j) and 4(k).

The second resultant strip 30 which has the consecutive separate liner 1 with at least one cut-and-tear line 2 therein, the ovally or circularly shaped medicament layer 3 and first elastic film layer 4 lied on said separated liner 1 and the ovally or circularly shaped adhesive layer 6 and second elastic film layer 7 lied just on said ovally or circularly shaped medicament layer 3 and first elastic film layer 4 is drawn up and transferred forward.

SIXTH STEP

Referring to Fig. 4(I), a die cutting is performed on the second resultant strip 30 into a predetermined shape (e.g. square shape), thus, producing a third resultant strip 32. At this stage, a scrap 86 of the separate liner 1 created from this die cutting is finally

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removed. The third resultant strips 32 make finished products of medicinal patch prior to packing for sale.

SEVENTH STEP

The finished products of the third resultant strip 32 are drawn up and transferred from the main die roller 60 to a conveyor 62 by a vacuum pad roller 90.

The method of making the medicinal patch for percutaneous administration comprises the abovedescribed seven steps and the present invention relates to a main unit to perform particularly from the third to seventh steps in the above.

Fig. 5 is a front view of an apparatus for performing said manufacturing steps for manufacturing medicinal patch for percutaneous administration in accordance with the present invention.

Reference numeral 100 denotes a frame of the apparatus for manufacturing the inventive medicinal patch P which is movable with a jack or jacks(not drawn), and made preferably from stainless steel. The first feed rollers 12 and 12' for mounting the roll of base film 10 and drawing it out are rollingly mounted on the frame up and down, so one of them unwinds the base film 10 selectively. If the base film roll mounted on any one of the upper and lower rollers 12 and 12' is all run out, a spare base film roll provided on the other feed roller starts to be drawn out without delay, which saves the loading time to enhance the productivity. These rollers 12 and 12' include a controller to minutely control the base film roll's mounting condition, a hand brake, a device for alarming decrement of the base film, and a sensor for detecting the cutting thereof(not shown).

A pair of rollers 40 and 41 which are so provided as to transfer the base film 10 control their rolling speed according to displacement of a dancer roller 42 having a balancer, and assures the constant-speed transfer of the base film. The dancer roller 42 keeps a predetermined weight by the balancer, and transfers the base film 10 to the main die roller 60 under a given tension regardless of the remained diameter of the base film roll wound around the feed roller 12 or 12'.

A cutting apparatus 44 which comprises a pair of the first die cutting rollers 14, 14' serves to half-die cut only the separate liner 1 of the base film 10 into a waveform. As the base film 10 passes between a pair of the first half-die cutting rollers 14 and 14' (first half-die cutting rollers), the separate liner 1 is half-die cut to have at least one continuous wave-shaped line 2 along its longitudinal direction.

Reference numeral 50 denotes a main unit of the apparatus for making the inventive medicinal patch. By the main unit 50 are performed the following five steps: one is the second half-die cutting by which the medicament layer 3 and the first elastic film layer 4 which are laminated over the separated liner 1 are processed into an oval or round shape; another is attaching the released adhesive tape 24 to the first resultant strip 18;

the next is is the third half-die cutting the adhesive tape into an oval or round shape; the next is performing a die cutting the resultant strip 32 to a predetermined shape (e.g. square shape) to produce finished products of medicinal patch P; and the last is finally drawing up the finished products by the vacuum pad roller 90 and moving them to the conveyor 62.

In reading the present specification, half-die cutting means that, when the sectional structure of a certain strip is made from more than two layers laminated, only the intended or predetermined layer/layers is/are to be cut among the laminated layers, whereas die-cut means to cut all the layers of the section at once. In connection with this, half-die cutting roller means a kind or piece of machine to perform half-die cut and die-cutting roller means a kind or piece of machine to perform die-cut.

A second half-die cutting roller 52 for half-die cutting only the medicament layer 3 and the first elastic film layer 4 into an oval or round shape, and a third half-die cutting roller 54 for half-die cutting only the adhesive tape into an oval or round shape, each have a plurality of oval or round-shaped kiss cutting blades equidistantly formed along their outer surfaces. A die cutting roller 59 also has a plurality of predetermined shaped, for example, quadri-shaped kiss cutting blades formed equidistant from one another at its outer surface and the detailed structure or configuration of the die cutting roller 59 can be seen in Fig. 7 which shows a perspective view of the part B shown in Fig. 6.

A plurality of vacuum holes(not drawn) are formed on the outer surface of the main die roller 60 for drawing up and transferring the base film 10 during the second, third half-die cutting steps and final die cutting step.

The preliminary and main pressure rollers 56 and 58 used for adhering the adhesive tape 24 over the first resultant strip 18 are interposed between the second half-die cutting roller 52 and the third half-die cutting roller 54. The preliminary pressure roller 56 is an auxiliary one, and the roller 58 is a main one. The process of rolling and compressing the released adhesive tape strip 24 against the first resultant strip 18 on the main die roller 60 prevents bonding failure(for example, air gap entrapped between the base film and the adhesive tape).

The vacuum pad roller 90 has rubber suckers(not drawn) on its outer surface for drawing up the finished products of medicinal patch from the surface of the main die roller 60 by suction, and transfers them to the conveyor 62.

During performing the process described in the above, the first release liner 5 of the base film 10 is collected on a first release liner winding roller 64 under a constant tension with the help of a powder clutch(not drawn) and a tension controller (TC1) regardless its winding diameter.

Reference numeral 66 denotes a roller on which a scrap 16 of the medicament layer 3 and the first elastic film layer 4 is wound. The scrap 16 is wound on the first

release liner winding roller 66 under a constant tension with the help of a powder clutch(not drawn) and a tension controller (TC2) regardless of the diameter of the scrap 16 wound.

The adhesive tape roll 20 is the second feed roller 22. Reference numeral 70 is a second release liner winding roller with a single-end fixing type shaft on which the second release liner 5 is collected after being separated from the adhesive tape 20.

An alarming system is provided to the second release liner winding roller 70 for informing an operator of the second release liner 5's being fully wound thereon. The winding tension is constantly kept by a powder clutch(not drawn) and a tension controller (TC3) when winding the release liner 5'.

Reference numeral 74 denotes a roller on `which the scrap 26 of the adhesive tape, produced after the third half-die cutting, is wound. An alarming system is also provided to the roller 74, thus informing the operator of the scrap 26's being fully wound on the roller 74. The tension of the strap 26 is constantly maintained by a powder clutch (not drawn)and a tension controller (TC4) when winding the scrap 26 on the roller 74.

A peeling roller 72 has a plurality of vacuum holes(not drawn) on its outer surface for drawing up the adhesive tape strip while separating the second release liner 5' from the adhesive tape strip 20. The adhesive tape strip, from which the second release liner 5' is separated by the peeling roller 72, becomes free from its beared tension by a dancer roller 77 having a given weight kept by a balancer, and avoids its gradual shrinking due to residual tensile stress when the released adhesive tape strip 24 is attached to the first resultant strip 18.

Reference numerals 76, 78, and 80 designate temporarily winding rollers, and these are positioned adjacent to the scrap winding roller 66, the second release liner winding roller 70, and the roller 74 on which the scrap 26 of the autiesive tape is wound, respectively. The rollers 76, 78, and 80 are used only when the scraps are fully wound on the rollers 66, 70, and 74, respectively and so the used ones are to be replaced with the new empty ones. All the rollers 76, 78, and 80 have a same role to save loading or replacing time. These rollers 76, 78, and 80 are preferably configured for non-viscidity to prevent the scraps from sticking to the outer surface of each of them.

Ovally or circularly punched portions 21 are serially formed on the scrap 26 of the released adhesive tape 24 by the third half-die cutting, as shown in Fig. 4(j), and in particular, its tensile strength becomes considerably lessen so that the scrap 26 is easily broken during its winding. Once the scrap 26 is broken, the apparatus cannot perform the next steps, thus lowering the productivity.

In connection with this, reference numeral 91 denotes a means for increasing the tensile strength of the scrap 26 and preventing cutting of the scrap 26 dur-

ing winding after the adhesive tape 24 is adhered to the first resultant strip 18. Preferably, the tensile stress reinforcing means is realized by thread or string provided to regions of the both longitudinal edges and/or middle portion of the punched scrap 26 of the adhesive tape 24

Fig. 6 shows an enlarged main part of the apparatus for manufacturing medicinal patch for percutaneous administration in accordance with the present invention, which corresponds to the part A of Fig. 5.

Fig. 7 is a perspective view of the second half-die cutting roller(part B of Fig. 6) in order to show structures of the second and third half-die rollers 52, 54 and diecutting roller 59(these three being substantially identical). Fig. 8 depicts sectional views of the main die roller 60 and vacuum pad roller 90 to show air passage 61 and vacuum holes 93 for vacuum sucking the patches from the main die roller.

From these Figs. 6 to 8, it can be understood that the second half die cutting roller 52 comprises largediameter parts 52A formed on both end; a small-diameter part 52B formed between said large-diameter parts; and a plurality of ovally or roundly shaped kiss cutting blades 52C equidistantly installed on outer surface of said small-diameter part, the height of said kiss cutting blades being a little lower than that of the differenc made by said large-diameter parts and small diameter part. Further, it can be also understood that since there are provided a plurality of vacuum holes 93 on the surface of the main die roller, the strip can be transferred in the condition of its close contact to the outer surface of the main die roller during processing steps of said second and third half-die cutting and die-cutting. The strip, under being transferred, is to pass the gaps formed by said difference of heights between the large-diameter parts and small-diameter part of said half-die cutting rollers and die cutting roller and, thus, is to be half-die cut or die cut by said kiss cut blades installed on the small diameter surface.

The following description relates to the operation of the apparatus for making the inventive medicinal patch P.

The base film 10, fed from one of the first feed rollers 12 and 12' at a required constant speed by a pair of transferring rollers 40 and 41, passes between the first half-die cutting rollers 14 and 14' so that only the separate liner 1 of the base film 10 is continuously half-die cut to have at least one wave-shaped cutting line 2(the first half-die cutting).

After the first half-die cutting, the released base film travels the outer surface of the main die roller 60 by closely vacuum contact thereon in accordance with the rolling movement of the main die roller and, then, the medicament layer 3 and the first elastic film layer 4 of the base film 10 are cut out by the oval or round kiss cutting blades equidistantly formed along the outer surface of the second half-die cutting roller 52.

The adhesive tape 24 produced from the adhesive

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tape roll 20 by peeling off the second release liner 5' therefrom is attached over the first resultant strip 18 with the help of the pressing rollers 56 and 58. In order to give more tensile stress to the scrap 26 of the adhesive tape 24, the thread or string 91 is provided to the back of the adhesive tape 24.

As the second resultant strip 30 formed by attaching the adhesive tape 24 to the first resultant strip 18 is moved a little way along the main die roller 60, the third half-die cutting roller 54, having a plurality of oval- or round-shaped kiss cutting blades equidistantly installed on its outer surface, half-die cuts only the adhesive tape 24 of the second resultant strip into an oval or round shape. A scrap 26 produced from the above process is wound on the roller 74 for removal. At this stage, the third half-die cutting is carried out on the regions of the adhesive tape 24 corresponding to the ovally or circularly shaped medicament and first elastic film layers 3 and 4.

The strip on which the third half-die cutting is performed is moved a little way along the main die roller 60 closely contacting the main die roller 60. The overall strip is then die cut out by the die cutting roller 59 which has a plurality of square-shaped kiss cutting blades formed equidistant from one another at its outer surface, thus producing finished products of medicinal patch P as shown in Fig. 1. The vacuum pad roller 90 draws up each finished product with its rubber suckers that are circumferentially formed equidistantly from each other, and transfers it to the conveyor 62. Automatic inspection and packing are performed on each finished product P of medicinal patch on the conveyor 62.

As described above, medicinal patch for percutaneous administration made by the apparatus according to the manufacturing steps of the present invention can fulfill the physical requirements of a transdermal skin patch. That is, the inventive medicinal patch can adhere to the skin of the knee or elbow securely and elastically for a long period of time even during bath or shower bath, and is not easily contaminated by the dirt without loss of medicinal properties. In addition, the oval- or round-shaped medicinal patch of the present invention is so thin and small that it can be securely attached to the skin of any diseased region of the human body, thus being superior to the presently-available transdermal skin patch.

Additional advantages and modifications will readily occur to those skilled in the art. Tie invention in its broader aspects is not limited to the specific details, and representative devices, shown and described herein. Accordingly, various modifications may be made without departing from the spirit or scope of the general inventive concept as defined by the appended claims and their equivalents.

Claims

1. An apparatus for manufacturing a medicinal patch

for percutaneous administration comprising:

a half-die cutting roller(a second half-die cutting roller) to ovally or roundly half die cut the medicament layer and first elastic film layer simultaneously laminated on a separate liner of a base film, said half-die cutting roller having large-diameter cylindrical parts, a small-diameter cylindrical part formed between said large-diameter cylindrical parts and a plurality of ovally or roundly shaped kiss cutting blades equidistantly installed on the outer surface of said small-diameter cylindrical part;

a scrap winding roller around which a scrap of the medicament and first elastic film layers produced by half-die cutting is wound for removal; a pressing means to press the adhesive tape laminated the base film on which ovally or roundly shaped medicament and first elastic film layers are formed by the second half-die cut so as to attach these with each other;

another half-die cutting roller(a third half-die cutting roller) which has a plurality of ovally or roundly half-die cutting blades equidistantly installed on its outer surface of small-diameter cylindrical part, performing continuous half-die cutting on regions of the adhesive tape attached to the base film into an oval or round shape, corresponding to the second half-die cut regions of the medicament and first elastic film layers;

a roller on which a scrap of the adhesive tape produced by the third half-die cutting is wound for removal;

a die cutting roller which has a plurality of quadri-shaped die cutting blades equidistantly installed on its outer surface, performing a continuous die cutting of a resultant strip which has the separate liner, the oval or circular shaped medicament and first elastic film layers and the oval or circular shaped adhesive and second elastic film layers, into a quadri-shaped shape; a roller on which a scrap of the resultant strip created by the die cutting is wound for removal; a main die roller having a plurality of vacuum holes on its outer surface for drawing up the separate liner of the base film, and with the outer surface thereof large diameter parts of all the half die cut rollers and die cut roller being in rollably contact; and,

a vacuum pad roller having a plurality of rubber sucking means on its outer surface for drawing up the finished products from the main die roller and transferring them to a conveyor.

An apparatus according to claim 1, wherein said pressing means comprises a pair of roller interposed between the second and third half-die cutting

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rollers, one of them being a preliminary pressure roller and the other being a main pressure roller.

- 3. An apparatus according to claim 1 or 2, further comprising means for adding more tensile strength to the scrap of the adhesive tape when it is removed after the third half-die cutting.
- **4.** An apparatus according to claim 3, wherein said tensile strength reinforcing means is a thread or string lengthwise provided to both longitudinal edges and/or middle portion of the adhesive tape.
- 5. An apparatus according to claim 1, further comprising temporarily winding rollers, each of which being adjacent to said medicament scrap winding roller, said second release liner winding roller, and said roller to wind the scrap of the adhesive tape respectively and used temporarily only when the scraps are fully wound on said three rollers.

FIG. 1(a)

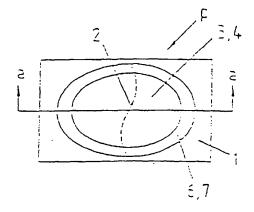


FIG. 1(b)

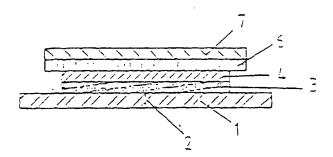


FIG. 2(a)

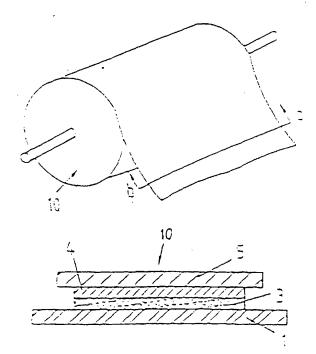
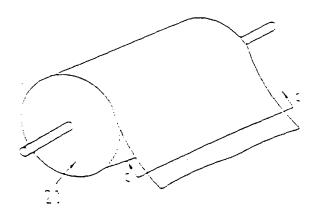


FIG. 2(b)



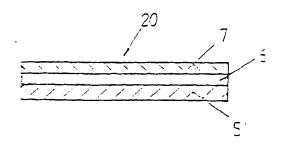


FIG. 3

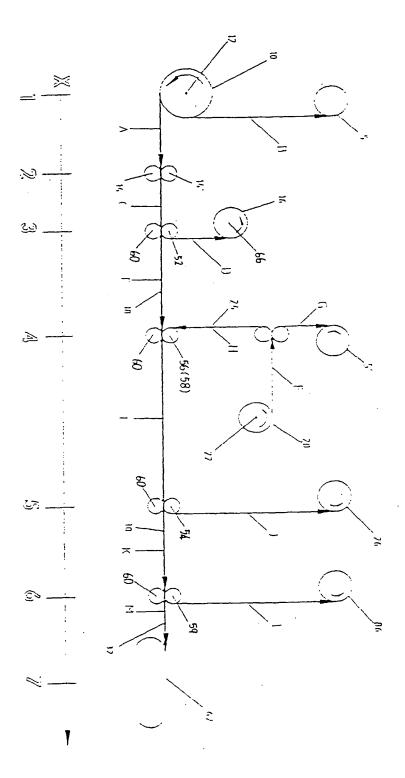


FIG. 4(a)

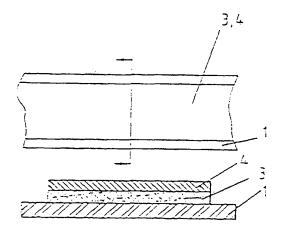


FIG. 4(b)

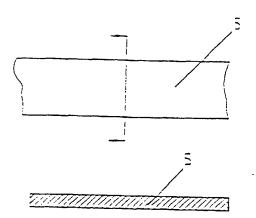


FIG. 4(c)

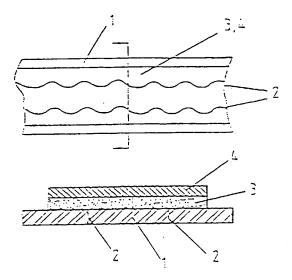


FIG. 4(d)

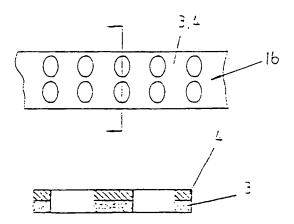


FIG. 4(e)

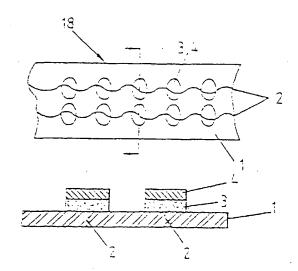


FIG. 4(f)

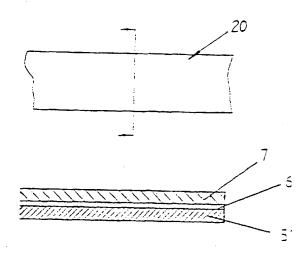


FIG. 4(g)

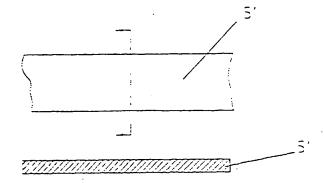


FIG. 4(h)

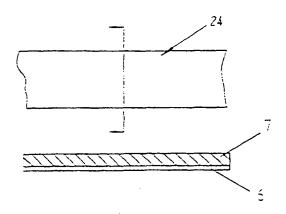


FIG. 4(i)

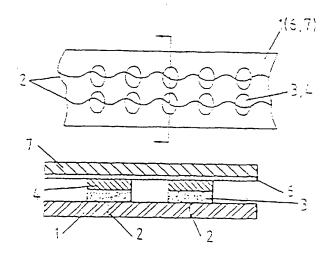


FIG. 4(j)

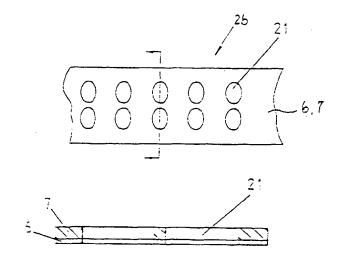


FIG. 4(k)

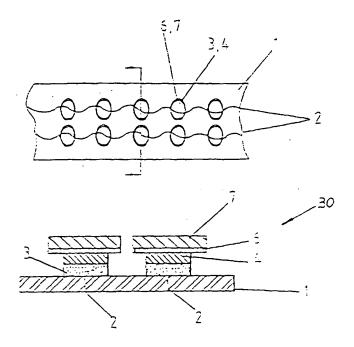


FIG. 4(1)

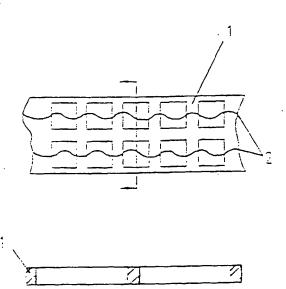
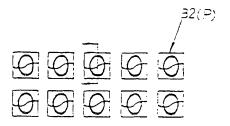


FIG. 4(m)



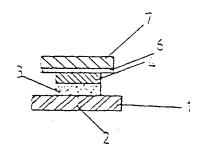


FIG. 5

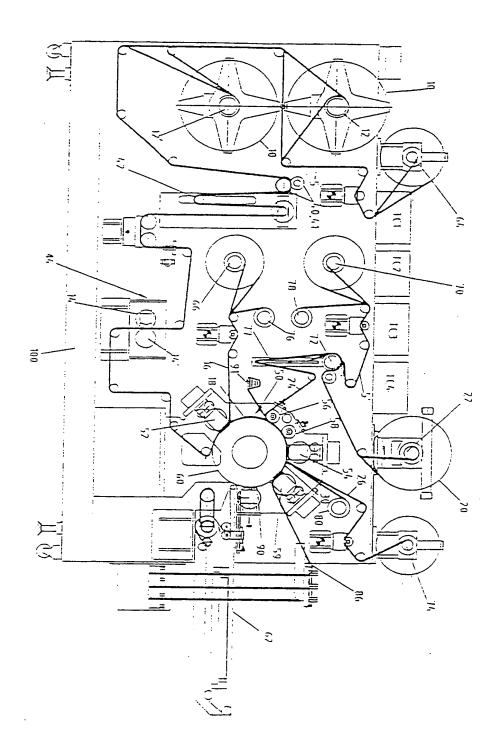
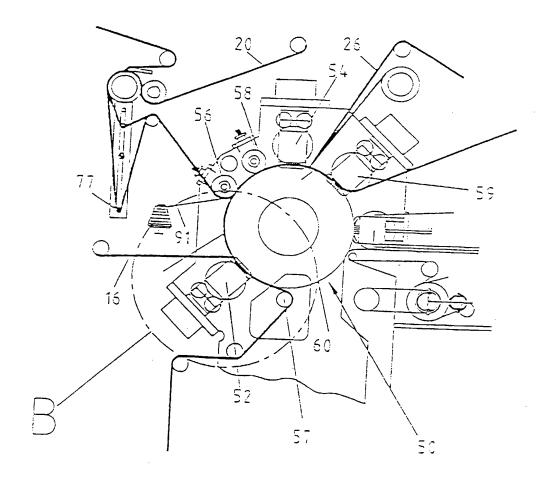
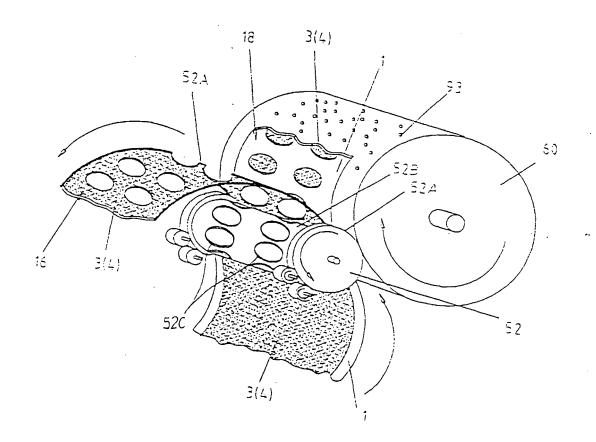
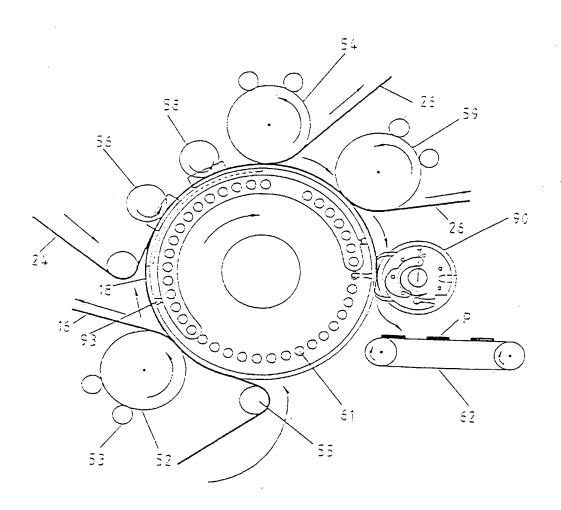


FIG. 6









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EP 0 848 937 A3 (11)

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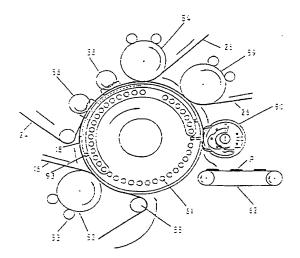
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Apparatus for manufacturing medicinal pathes for percutaneous administration (54)

Apparatus for manufacturing medicinal patches (57)for percutaneous administration, particularly a main processing unit which performs processing steps such as half die cutting, bonding and die cutting on the base film strip and adhesive tape strip. A half-die cutting roller (52) to simultaneously half die cut the medicament layer and first elastic film layer; a scrap winding roller (66) to collect the scrap; a pressing means (56,58) to press the adhesive tape laminated to the base film; another halfdie cutting roller (54) performing half-die cutting on regions of the adhesive tape attached to the base film; a roller (74) on which a scrap of the adhesive tape produced by the half-die cutting is wound for removal; a die cutting roller (59), performing a continuous die cutting of a resultant strip; a main die roller (60) having a plurality of vacuum holes on its outer surface and a vacuum pad roller (90) for drawing up the finished products from the main die roller and transferring them to a conveyor.





EUROPEAN SEARCH REPORT

Application Number

EP 97 12 2411

	DOCUMENTS CONSID		1	<u> </u>
Category	Citation of document with ir of relevant pass	ndication, where appropriate, ages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.C1.6)
A	WO 92 19451 A (NOVE 12 November 1992 (1 * abstract; claims;	992-11-12)	1-5	A61F13/02
A	US 2 680 943 A (PET 15 June 1954 (1954-	ERSEN) 06-15)		
Α	WO 94 21207 A (MINN 29 September 1994 (ESOTA MINING & MFG) 1994-09-29)	,	٠.
A	EP 0 571 700 A (MLI 1 December 1993 (19	ACQUISITION CORP II) 93-12-01) 		
				TECHNICAL FIELDS
				SEARCHED (Int.Cl.6)
				A61F
-				
	The present search report has b	een drawn up for all claims		
-	Place of search	Date of completion of the search		Examiner
	THE HAGUE	24 September 19	999 Soe	derberg, J
X : partic Y : partic docur A : techn	TEGORY OF CITED DOCUMENTS cularly relevant if taken alone cularly relevant if combined with anothment of the same category bological background written disclosure	E : earlier patent atter the filing er D : document cit L : document cite	ciple underlying the in document, but publis	nvention shed on, or

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 97 12 2411

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

24-09-1999

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9219451	A	12-11-1992	AU CA EP SG US	2004092 A 2109099 A 0592481 A 43349 A 5405486 A 5656285 A	21-12-199 26-10-199 20-04-199 17-10-199 11-04-199 12-08-199
US 2680943	Α	15-06-1954	NONE		
WO 9421207	A	29-09-1994	AU AU BR CA CN EP JP US US	682853 B 6237494 A 9405902 A 2157040 A 1121309 A 0690706 A 8508417 T 5531855 A 5738642 A	23-10-199 11-10-199 26-12-199 29-09-199 24-04-199 10-01-199 10-09-199 02-07-199 14-04-199
EP 0571700	Α.	01-12-1993	AU CA JP KR MX	2600692 A 2078960 A 6296702 A 9607519 B 9300566 A	28-10-199 22-10-199 25-10-199 05-06-199 01-10-199
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